



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

January 15, 1992

MEMORANDUM

SUBJECT: Interpretation of the Good Laboratory Practice (GLP)
Regulation

GLP Regulations Advisory No. 40

FROM: David L. Dull, Director
Laboratory Data Integrity Assurance Division

TO: GLP Inspectors

Please find attached an interpretation of the GLP regulations as issued by the Policy & Grants Division of the Office of Compliance Monitoring. This interpretation is official policy in the GLP program and should be followed by all GLP inspectors.

For further information, please contact Francisca E. Liem at FTS 398-8333 (703) 308-8333.

Attachment

cc: C. Musgrove



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Dear

This is in response to your letter of November 11, 1991. In your letter you requested a waiver of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Good Laboratory Practices (GLP) requirement at 40 CFR part 160.105(c), which require the assignment of test substance storage containers for the duration of a study.

Your request is in reference to your 1991/1992 terrestrial field study where large amounts of pesticide are in use as part of the study, with applications in October of 1991 and March of 1992. You stated that there would be a large number of containers and that the long term retention and storage of these containers would represent a safety hazard and potential conflicts with state and local regulations. You proposed to perform certain steps to assure container accountability in lieu of retaining the actual containers for the duration of the study.

EPA believes that the provision for assignment of storage containers for the duration of the study at 40 CFR 160.105(c) is a logical and necessary provision that in most cases provides accountability of test material in a manner that imposes no unusual burden. In your particular case; however, the number of containers may pose unusual safety and incumbrance problems.

Our staff has reviewed your request in light of the need to provide complete accountability of test material and the potential burden involved in storing and accounting for approximately 1600 containers. It is our opinion that certain record keeping steps could provide a basis for establishing an acceptable alternate method for the accounting of test substance storage containers in lieu of actual storage of the containers for the duration of this study, and are willing to allow a conditional exception to this requirement.

This exception is applicable only to the study that you described in the confidential attachment to your letter of November 11, 1991, and is conditional on the following:

- 1) N shall assure the following records are maintained as

raw data for this study: (a) information of shipments pertaining to each container leaving the storage site (examples of such records are shipping request records, bills of lading, carrier bills, and monthly inventories of warehouse activity); (b) test article receipt records at each testing facility; (c) complete use logs of material taken from containers; (d) a record of the final destination of the container, including the place and date of disposal or reclaiming, and any appropriate receipts.

- 2) A statement shall be included with the statement of compliance or noncompliance required at 40 CFR 160.12 describing that this exception to Good Laboratory Practices is in accordance with the conditions provided in this letter.
- 3) shall prepare an inventory of empty containers before disposal, including sufficient information to uniquely identify containers, and shall maintain this inventory in an up-to-date manner recording all arrivals of empty containers and their disposal. This record shall be maintained as raw data for this study.
- 4) shall identify the locations of facilities where test material is stored; where empty containers are stored prior to disposal; where records of use, shipment, and disposal of containers are maintained and where the test substance is used in studies (i.e., testing facility) Within two weeks of receipt of notification of any pending inspection involving this study, N shall report the location of each of these facilities to:

David L. Dull, Director
Laboratory Data Integrity Assurance Division
Office of Compliance Monitoring (EN-342W)
Office of Pesticides and Toxic Substances
U.S. Environmental Protection Agency
401 M Street SW
Washington, DC 20460

Should these conditions not be fully met, all of the provisions of 40 CFR 160 (GLPs), including assignment of storage containers for the duration of the study, apply.

In addition, is reminded that storage, disposal, or recycling of containers must be done in a manner pursuant to all applicable Federal, State, County, or local laws.

If you have questions concerning this response, please contact Steve Howie of my staff at (703) 308-8290.

Sincerely yours,

/s/ John J. Neylan III, Director,
Policy and Grants Division
Office of Compliance Monitoring

cc: David L. Dull
GLP File